The Pesticide Unit in the new EFSA structure: tasks, challenges, vision

Herman Fontier

Content

- EFSA and the new structure
- The new Pesticides Unit and its tasks
- The vision of the Pesticides Unit

What is EFSA

- European Food Safety Authority, Parma
- Created by Regulation (EC) No 178/2002 (the so-called food law)
- EFSA's role is to assess and communicate on all risks associated with the food chain

What is EFSA

- All of EFSA's activities are guided by a set of key values:
  - Openness and transparency
  - Excellence in science
  - Independence
  - Responsiveness

New EFSA structure

- 3 scientific directorates (instead of 2)
  - Scientific Strategy and Coordination
  - **Scientific Evaluation of Regulated Products**
    - **Application Desk**
    - Feed
    - Nutrition
    - Food Ingredients & Packaging
    - GMO
    - **Pesticides**
  - Risk Assessment and Scientific Assistance

Reasons for the change

- Reflect the increasing workload on applications and improve service to applicants
- Consolidate resources for public health priorities (chemical and biological contaminants) and animal/plant health
- Prepare EFSA for future evolutions (financing of the activities, evolving role of panels,…)

Timing

- No “big bang” scenario, but step-by-step approach
- Gradual migration from 01/05/2011 to 01/01/2012
- The new Pesticides Unit has been put in place on 01/05/2011

REPRO Directorate

- The Scientific Evaluation and Regulated Products Directorate is created in order to:
  - Bring together Units dealing with applications
  - Harmonise working methods
  - Have more flexibility in distribution of workload and in handling of peak periods
  - Be more client focused by creating a front office function (Application Desk)
  - Strengthen the focus on science by centralising certain administrative tasks

Application Desk

- Coordinate and streamline processes within the Units dealing with applications
- First focus: standardisation of administrative aspects of dossier handling + help desk
- Step-by-step design of processes and services within the next months
- Recruitment procedures are ongoing

Pesticides Unit

- Pesticides Unit = PRAPeR Unit + PPR Unit
- Benefits:
  - More input from the practice (former PRAPeR) in the development of guidance documents
  - More flexibility in resource management

Tasks of the Pesticides Unit

- Development of guidance documents for the risk assessment of pesticides
- Scientific opinions an questions related to pesticides
- Conclusions on active substances
- Reasoned opinions on maximum residue levels (MRLs)
- Annual Report on Pesticide Residues

PPR Panel

PLANT PROTECTION PRODUCTS AND THEIR RESIDUES (PPR) Panel

Development and revision of **EU guidance documents** for pesticide assessment to promote harmonised scientific approach in pesticide risk assessment (e.g. cumulative exposure assessment of pesticide residues)

Scientific opinions on generic issues (e.g. data requirements for pesticide dossiers)

Questions on risk assessment for **specific pesticides** (e.g. potential risk of developmental neurotoxicity of deltamethrin)

PLANT PROTECTION PRODUCTS AND T
RESIDUES (PPR) Panel

XXX

55 scientific opinions since 2003

WGs **Toxicology**

WG **Fate and behaviour**

PPR Panel **21 experts**

WGs **Residues**

WG **Eco-toxicology**

Supported by EFSA Secretariat

Pesticide Risk Assessment Peer Review

Peer Review of pesticides under Directive 91/414/EEC (now replaced by Regulation (EC) No. 1107/2009)

Risk assessment of pesticide residues under Regulation (EC) No. 396/2005 in the framework of setting and reviewing maximum residue levels (MRLs)

Preparation of **Annual Report on Pesticide Residues**

Pesticide Risk Assessment Peer Review

255 EFSA conclusions

In collaboration with MS experts:
Assessment of pesticides

Toxicology
incl. operator exposure

Fate and behaviour in the environment

EFSA Conclusions on pesticides

Residues
incl. consumer exposure

Ecotoxicology

Physical and chemical properties

Methods of analysis

Setting maximum residue levels (MRLs)

EFSA Conclusions on pesticides

Setting maximum residue levels (MRLs)

215 EFSA reasoned opinions/ technical reports

Need to set new,
amend or delete existing MRLs

Post-marketing surveillance

Use of pesticides on crops

Monitoring of pesticide residues on food available to European consumers

MS report the results of pesticide monitoring to EFSA

Data analysis by EFSA
Exposure assessment

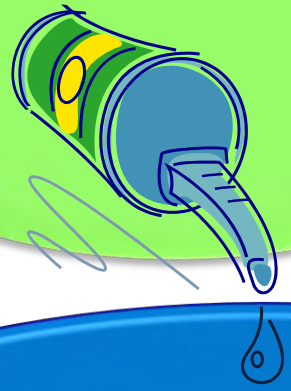
2 Annual Reports

Annual Report on Pesticide Residues

Pesticides Unit

efsa
European Food Safety Authority

PPR Panel
Guidance documents



Reg. 396/2005
MRLsetting, pesticide monitoring

Reg. 1107/2009
Dir. 91/414
Evaluation of active substances (representative uses)

PRAPeR's Networks
Pesticide Steering Committee

Planning and **monitoring** of the risk assessment process

Integration of risk assessment and MRL setting **processes**

Coordination with ECHA

Advice on **prioritisation** in development and updating of risk assessment **guidance documents**

PRAPeR's Networks
Networking Group on Pesticide Monitoring

Consultation forum for all matters related to pesticide residues monitoring

Preparation of the **Annual Reports** on Pesticide Residues

Review of **data model** for reporting results

Review of **methodology** to assess **consumer dietary exposure** to pesticide residues in food

Vision for the Unit

Deliver within the legal or agreed time lines, as an independent scientific organisation, in a context permitting an adequate mid- and long-term planning, and in consultation with the European Commission and the Member States, fit for purpose high quality scientific outputs, ensuring a full transparency of the process leading to their adoption and of the rationale behind the main findings and recommendations

Vision

- In the next slides, we will examine how far we are with the implementation of this vision, what has already been achieved, what needs to be further improved, what are the challenges we are facing

Respect of time lines

Deliver **within the legal or agreed time lines**, as an independent scientific organisation, in a context permitting an adequate mid- and long-term planning, and in consultation with the European Commission and the Member States, fit for purpose high quality scientific outputs, ensuring a full transparency of the process leading to their adoption and of the rationale behind the main findings and recommendations

Respect of time lines

- Challenge: how to reconcile respect of time lines with high quality of scientific output?
- Conclusions on active substances: major improvements have been achieved in meeting the time lines (focussed peer review, streamlined conclusions)
- Annual Report on Pesticide Residues: outsourcing of preparatory work

Respect of time lines

- Reasoned opinions on MRLs:
  - outsourcing of preparatory work for Article 12 reasoned opinions
  - Article 10 reasoned opinions
- Panel output (guidance documents, scientific opinions): efforts to make a realistic planning, build further on dialogue with European Commission for agreeing on time lines in consensus

Independence

Deliver within the legal or agreed time lines, as an **independent scientific organisation**, in a context permitting an adequate mid- and long-term planning, and in consultation with the European Commission and the Member States, fit for purpose high quality scientific outputs, ensuring a full transparency of the process leading to their adoption and of the rationale behind the main findings and recommendations

Independence

- EFSA has a clear and transparent policy in place ensuring the independence of its outputs (annual declarations of interests of all experts)
- Challenge: wrong perception by public, for instance as a result of deliberate misrepresentations of EFSA's outputs => further need for communication on EFSA's policy on independence

Planning

Deliver within the legal or agreed time lines, as an independent scientific organisation, in a **context permitting an adequate mid- and long-term planning**, and in consultation with the European Commission and the Member States, fit for purpose high quality scientific outputs, ensuring a full transparency of the process leading to their adoption and of the rationale behind the main findings and recommendations

Planning

- Closely linked to the question of the time lines
- Challenge: the Pesticides Unit has little or no control over the incoming workflows (depends on industry applications, Commission Regulations, mandates sent by the Commission)
- The Regulation (EC) No 1107/2009 will lead to new tasks (for instance basic substances); what will be the workload linked to these?

Planning

- Constant dialogue with Commission, EFSA/Commission initiative concerning mid-term planning, collection of information from Member States (Networks), contacts with applicants

In consultation with EC and MSs

Deliver within the legal or agreed time lines, as an independent scientific organisation, in a context permitting an adequate mid- and long-term planning, and in **consultation with the European Commission and the Member States**, fit for purpose high quality scientific outputs, ensuring a full transparency of the process leading to their adoption and of the rationale behind the main findings and recommendations

In consultation with EC and MSs

- EC and MSs are major « clients » of EFSA (for decision making, for national authorisations)
- EC is also a major « employer » of EFSA
- Close cooperation with both EC and MSs is a key element; therefore the Pesticides Unit:
  - Has established 2 networks with MSs representatives: the Pesticide Steering Group and the Networking Group on Pesticide Monitoring
  - Has every 2 weeks a teleconference with the Commission and is attending all meetings of the Standing Committee related to pesticides

In consultation with EC and MSs

- MSs get an opportunity to comment on certain draft outputs
- MSs are consulted on issues such as protection goals

Fit for purpose

Deliver within the legal or agreed time lines, as an independent scientific organisation, in a context permitting an adequate mid- and long-term planning, and in consultation with the European Commission and the Member States, **fit for purpose** high quality scientific outputs, ensuring a full transparency of the process leading to their adoption and of the rationale behind the main findings and recommendations

Fit for purpose

- Challenge: reconcile the concept of what is fit for purpose from the perspective of our “clients” with the EFSA key values; i.e. pragmatism and risk manager considerations versus excellence in science and independence
- Perception: the guidance documents are too complex, the conclusions are too conservative (or not enough for certain stakeholders)
- Further dialogue and communication is needed; need for understanding each others positions

Quality

Deliver within the legal or agreed time lines, as an independent scientific organisation, in a context permitting an adequate mid- and long-term planning, and in consultation with the European Commission and the Member States, fit for purpose **high quality scientific outputs**, ensuring a full transparency of the process leading to their adoption and of the rationale behind the main findings and recommendations

Quality

- EFSA has put in place several tools for quality assurance (internal review, external review)
- An overall EFSA policy on quality management is under preparation

Transparency of the process

- Deliver within the legal or agreed time lines, as an independent scientific organisation, in a context permitting an adequate mid- and long-term planning, and in consultation with the European Commission and the Member States, fit for purpose high quality scientific outputs, ensuring a full **transparency of the process** leading to their adoption and of the rationale behind the main findings and recommendations

Transparency of the process

- The outputs describe in detail the process that has led to their adoption
- Public and stakeholders' consultations take place
- Member States are consulted on most types of draft outputs

Transparency of the science

- Deliver within the legal or agreed time lines, as an independent scientific organisation, in a context permitting an adequate mid- and long-term planning, and in consultation with the European Commission and the Member States, fit for purpose high quality scientific outputs, ensuring a full **transparency** of the process leading to their adoption and **of the rationale behind the main findings and recommendations**

Transparency of the science

- The outputs are where relevant published together with background documents; for instance all documents related to the peer review process are published along with the conclusions on active substances

Conclusion

- Many elements of the vision are already to a large extent realised, in particular with regard to transparency, independence, quality, consultation with EC and MSs
- Certain aspects need further attention, in particular meeting the time lines, planning in the mid- and long-term, the perceived level of adequacy (fit for purpose) of some types of output

Thank you for your attention!